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510(k) Summary

510(k) Owner:

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Trade Name of Device:

Solitaire™ FR Revascularization Device

Common Name of Device:

Catheter, Thrombus Retriever

Classification of Device:

21 CFR 870.1250 – Class II

Predicate Device:

Merci® Retrievers (K062046, K063774, K070521, K071172, K081305, K082034, K090085)

Device Description:

The Solitaire™ FR Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The device is intended for use in the neurovasculature such as the internal carotid artery, M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries. The device is a nitinol self-expanding, fully retrievable, stent-based design that allows for clot retrieval when deployed in occluded target vessels after acute ischemic stroke. The distal nitinol portion of the device facilitates clot retrieval and has Pt-Ir radiopaque markers for visualization on the proximal and distal ends. The device is supplied sterile and is intended for single-use only by physicians trained in interventional neuroradiology and treatment of ischemic stroke.

Intended Use:

The Solitaire™ FR Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA).or who fail IV t-PA therapy are candidates for treatment.

Comparison of Technological Characteristics to Predicate Device

The Solitaire FR device is substantially equivalent to the Merci Retriever based on the successful completion of non-clinical bench and animal testing, clinical testing, and similar principles of operation and indications for use.

	Merci Retriever	Solitaire FR
Indication for Use	The Merci Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The Merci Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.	The Solitaire™ FR Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Materials	Nitinol core wire Platinum distal coil Polymer filaments Hydrophilic coating	Nitinol device and push wire 90% Platinum/ 10% Iridium distal marker coils Stainless steel wire, Parylene coated Dymax adhesive PTFE push wire shrink tubing PTFE/Grilamid introducer sheath
Bench Testing	Overall rate of successful clot retrieval was 80% in an *in vitro* tortuous anatomical model.	Overall rate of successful clot retrieval was 96.2% in an *in vitro* tortuous anatomical model.
Acute Animal study	Successful clot retrieval was 66.7% (4/6). Arterial histological response was substantially equivalent to the Solitaire devices.	Successful clot retrieval was 100% (6/6). Arterial histological response was substantially equivalent to the Merci devices.
Chronic Animal Study	Acute results: Successful clot retrieval was 66.7% (4/6) and recanalization was 83.3% (5/6). Chronic results: Successful clot retrieval was 100% (8/8); recanalization after chronic period was 50% (4/8). Arterial histological response was substantially equivalent to the Solitaire devices.	Acute results: Successful clot retrieval and recanalization was 100% (6/6). Chronic results: Successful clot retrieval was 87.5% (7/8); recanalization after chronic period was 75% (6/8). Arterial histological response was substantially equivalent to the Merci devices.
Clinical trial SWIFT (G090082)	Merci group success rate for the primary effectiveness endpoint = 24.1% (13/54)	Solitaire group success rate for the primary effectiveness endpoint = 60.7% (34/56)

Preclinical Performance Data:

Non-clinical bench and animal testing as well as a multi-center, randomized, prospectively controlled clinical trial comparing the performance of Solitaire FR to the Merci Retriever were performed. The Solitaire FR devices met test specifications and the non-inferior outcome measures of the clinical protocol.

Test	Results	Conclusion
L929 MEM Elution Test – ISO	Grade 0 reactivity observed 48 hours post exposure to test article extract	Non-cytotoxic
L929 MTT Cytotoxicity Test (1 concentration) – ISO	Test article viability = 83%	Non-cytotoxic
Kligman Maximization Test – ISO	0% (Grade I), weak allergenic potential	Non-sensitizer
Intracutaneous Injection Test – ISO	Difference of overall mean score between test article and control was 0.0	Non-irritant
Systemic Injection Test – ISO	No animals injected with test article showed significantly greater biological reaction than animals treated with control	Not systemically toxic
Rabbit Pyrogen Test (Material Mediated) – ISO	Temperature increases for test animals were 0.0, 0.0, and 0.0°C. Control = 0.0°C	Non-pyrogenic
90-Day Systemic Toxicity in Rats via Subcutaneous Implantation	Bioreactivity rating at 90 days = 0.7	Not locally or systemically toxic
Intramuscular Implantation Test – ISO 4 week Implantation	Bioreactivity rating at 4 weeks = 2.1	Non-reactive
Intramuscular Implantation Test – ISO 13 week Implantation	Bioreactivity rating at 13 weeks = 0.0	Non-reactive
Salmonella Typhimurium and *Escherichia Coli* Reverse Mutation Assay – ISO	A statistically significant increase was not observed with test articles as compared to controls	Non-mutagenic
In Vitro Mouse Lymphoma Assay with Extended Treatment	Non-mutagenic; acceptable negative and positive controls results for CE and MF	Non-mutagenic
Rodent Bone Marrow Micronucleus Assay (90 Animals) – ISO	Non-clastogenic; no statistically significant increase ($p \geq 0.05$)	Non-clastogenic
Unactivated Partial Thromboplastin Time Assay – ISO Indirect Contact	UPTT of plasma exposed to test article was not significantly decreased when compared to controls	No adverse effect on clotting time of human plasma
Prothrombin Time Assay – ISO Indirect Contact	Difference < 1 sec	No adverse effect on prothrombin coagulation time of human plasma
Hemolysis – Rabbit Blood – ASTM Indirect Contact	Test article = 0.0% hemolysis	Non-hemolytic

Test	Results	Conclusion
In Vitro Hemocompatibility Assay – ISO Indirect Contact	Test article had no adverse effects on any hematological parameters tested (complete blood count, hematocrit, erythrocyte indices, and platelet count)	No adverse effects on hematological parameters of human blood
In-Vivo Thrombogenicity Assay (Dog)	Vessel Patency ≤ 1 Thrombus ≤ 1 Pulmonary Thromboembolism = 0	The Solitaire FR test devices have similar thromboresistance characteristics as the control devices (Merci)
Complement Activation C3a	Solitaire 1.7% as compared to activation by positive control Merci 1.7% as compared to activation by positive control	The level of C3a complement activation induced by Solitaire FR was similar to the control device (Merci)
Complement Activation SC5b-9	Solitaire 0.0% as compared to activation by positive control Merci 0.2% as compared to activation by positive control	The level of SC5b-9 complement activation induced by Solitaire FR was similar to the control device (Merci)
Total Length	N = 62; all devices within specification	Pass
Delivery Force	N = 61; all devices below peak force specification	Pass
Re-sheathing Force	N = 61; all devices below peak force specification	Pass
Durability	N = 60; all devices completed delivery, deployment and recovery without any observations	Pass
A_f Temperature	N = 23; all devices within A_f temperature specification	Pass
Kink Resistance	N = 62; all devices deployed to intended location and resisted kinking	Pass
System Tensile Strength	N = 30; all devices above tensile strength specification	Pass
Markercoil Tensile Strength	N = 123; all devices above tensile strength specification	Pass
Torque Response	N = 60; all devices within torque response specification	Pass
Torque Strength	N = 60; all devices within torque strength specification	Pass
Radial Force	N = 67; all devices within radial force specification	Pass
Radiopacity	N = 2; all markerbands visualized effectively with tissue and bone simulation	Pass

Clinical Performance Data

Study Design:

The SWIFT (Solitaire™ FR with the Intention for Thrombectomy) Study is a multi-center, IDE, randomized, prospectively controlled Study comparing the performance of the Solitaire™ FR Revascularization Device with a commercially available Merci® Retriever. Randomization to the Solitaire FR arm or Merci arm occurred on a 1:1 basis. Assessments for the primary efficacy endpoint were done post procedure and subjects were followed for up to 90 days (±15days) for neurological outcomes and safety assessments.

Sample Size:

A total of 144 Subjects contributed to the ITT (intention-to-treat) population of which 31 (21.5%) were Solitaire FR roll-in (non-randomized), 58 (40.3%) were randomized to Solitaire FR and 55 (38.2%) were randomized to Merci. Comparative analyses for the purpose of study endpoints were based solely upon the ITT ***randomized*** study population.

Statistical Analysis:

All subjects who were consented and randomized were included in the ITT population. The ITT population included all subjects with data for a given endpoint; results were assessed according to randomized assignment regardless of the treatment actually received. The per-protocol (PP) population excluded those subjects who failed to meet all inclusion and exclusion criteria or who did not receive treatment with the randomly assigned device.

The primary efficacy analysis (successful recanalization measured by TIMI flow without symptomatic hemorrhage) was performed using a one-sided test under Blackwelder's method of testing non-inferiority at the 0.025 level of significance. The primary safety endpoint of device- and/or procedure-related Serious Adverse Events (SAEs) was evaluated descriptively.

Additional analyses included subgroup and interim analyses. Subgroup analyses, based on the vessel site treated and baseline NIHSS, were performed to assess homogeneity of the primary efficacy endpoint. An interim analysis was performed, after enrolling 144 roll-in and randomized subjects, to obtain a statistical look for efficacy and forms the basis for this report.

Study Procedures:

Angiographic data obtained during the study included a baseline angiogram (prior to device deployment). A post study device use angiogram was conducted immediately after completion of study device use, i.e. after achievement of TIMI 2 or 3 reperfusion or 3 passes of the study arm device without recanalization. If any rescue therapy was employed, a final post all procedures angiogram was done. Post study device use angiographic data was used to assess the primary endpoint by the Core Lab (blinded to treatment assignment). Follow up evaluations included a 24 hour (±6 hours) follow-up visit that included an NIHSS examination and CT or MRI imaging. Subsequent follow-up visits occurred at 7-10 days (or discharge if earlier), 30 days (±15days), and 90 days (±15days) in which the modified Rankin Scale (mRS) assessing global disability, the Barthel Index assessing instrumental activities of daily living, and the NIHSS exam assessing neurologic deficit were performed.

Inclusion Criteria:

- Subject or subject's legally authorized representative has signed and dated an Informed Consent Form
- Age 22 – 85
- Clinical signs consistent with acute ischemic stroke
- NIHSS $\geq$ 8 and < 30
- Thrombolysis in Myocardial Infarction (TIMI) 0 or TIMI 1 flow in the M1 or M2 of MCA, ICA, basilar or vertebral arteries confirmed by angiography that is accessible to the Solitaire FR or Merci Device

- Subject is able to be treated within 8 hours of stroke symptoms onset with minimum of one deployment of the Solitaire FR or Merci Device.
- Subject who is ineligible or failed intravenous tissue plasminogen activator (t-PA) therapy given at local institutions or within national practice. (Note: Failed IV t-PA is defined as subjects with occlusion present 61 minutes or more after start of IV therapy.)
- Subject is willing to conduct follow-up visits.

Exclusion Criteria:

- NIHSS ≥ 30 or coma
- Neurological signs that are rapidly improving prior to or at time of treatment
- Females who are pregnant or lactating
- Known serious sensitivity to radiographic contrast agents
- Current participation in another investigation drug or device study
- Uncontrolled hypertension defined as systolic blood pressure > 185 or diastolic blood pressure > 110 that cannot be controlled except with continuous parenteral antihypertensive medication
- Use of warfarin anticoagulation with INR > 3.0
- Platelet count < 30,000
- Glucose < 50 mg/dL
- Arterial tortuosity that would prevent the device from reaching the target vessel
- Life expectancy of less than 90 days
- Additionally, subjects were also considered ineligible for study participation if they met any of the following imaging exclusion criteria
- CT or MRI evidence of hemorrhage on presentation
- CT showing hypodensity or MR showing hyperintensity involving greater than 1/3 of the middle cerebral artery (MCA) territory (or in other territories, >100 cc of tissue) on presentation
- CT or MRI evidence of mass effect or intracranial tumor (except small meningioma)
- Angiographic evidence of carotid dissection, complete cervical carotid occlusions, or vasculitis

Reason for Screen Failure	Occurence
Angiographic	**91**
No occlusion on angiogram	35
Complete cervical carotid occlusion	28
Occlusion located in ineligible vessel	16
Vessel tortuosity	7
Vessel dissection	5
Clinical	**234**
NIHSS does not qualify for study	81
Age	38
Neurological signs improvement	34
Stroke onset time unknown	29
Time from stroke onset exceed 8 hrs	23
Exclusion criteria not documented	11
Unable to consent	11
No intervention per physician	2
INR exceed required limit	2
Uncontrolled hypertension	1
Subject presented comatose	1
Pre-existing condition, tumor	1
Imaging	**55**
CT/MRI showing infarct	23
Hemorrhage present at baseline	22
Imaging exclusion specific not listed	5
Infarct involving greater than 1/3 of the MCA territory	4
No mismatch on MRI	1
Other	**11**
Total	**391**

Primary Safety and Efficacy Outcomes:

Analysis of the primary efficacy endpoint showed statistically significant evidence that Solitaire FR was non-inferior to the Merci device in the arterial recanalization of occluded target vessels without any presence of symptomatic intracranial hemorrhage. The Solitaire FR group success rate was 60.7% (34/56) compared to 24.1% (13/54) for the Merci group. The criterion for non-inferiority was met with an associated ***p<0.0001***.

Key Secondary Outcomes:

- Time to achieve initial recanalization: A statistically significant difference between the two devices was observed (Solitaire FR 47.0 minutes vs. Merci 58.7 minutes), ***p=0.0376.***
- Assessment of neurological outcomes at Day 30 and Day 90:
  - At day 30, GNO (good neurological outcome) with Solitaire FR (50.9%) was higher than Merci (33.3%).
  - At day 90, GNO with Solitaire FR (58.2%) was higher than Merci (33.3%).

- The overall mortality rate for the subjects randomized to Merci was 38.2%, which was higher than the mortality rate for the subjects randomized to Solitaire FR, 17.2%. The mortality profile of the roll-in Solitaire FR subjects was similar to that of randomized Solitaire FR subjects at 16.1%. There was one device related death observed in the study attributed to the Merci device and none attributed to the Solitaire FR device.
- The rate of symptomatic intracranial hemorrhage was 10.9% in the Merci group and 1.7% in the Solitaire FR group and the rate of all intracranial hemorrhage was 38.2% in the Merci group and 17.2% in the Solitaire FR group.

Important Safety Results:

The nominal overall device- and/or procedure-related serious adverse event rate for Solitaire FR subjects was observed to be lower than for Merci subjects (22.4% vs. 40.0%). This pattern persisted in device-related events only, while the event rate point estimates for procedure-related events were comparable between randomized groups.

Adverse Events occurring at an incidence of 5% or more in any group in the SWIFT Trial					
MedDRA Preferred Term	**Roll-in (all SOLITAIRE™ FR device)**	**Randomized SOLITAIRE™ FR device**	**Randomized Concentric Medical MERCI™ device**	**All Enrolled**	**Rand. p-value**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]	
TOTAL Adverse Events (AE)	**83.9% (26/31) [115]**	**94.8% (55/58) [267]**	**92.7% (51/55) [262]**	**91.7% (132/144) [644]**	**0.430**
Blood and Lymphatic System Disorders	**22.6% (7/31) [8]**	**24.1% (14/58) [17]**	**16.4% (9/55) [9]**	**20.8% (30/144) [34]**	**0.355**
Anaemia	19.4% (6/31) [6]	20.7% (12/58) [13]	12.7% (7/55) [7]	17.4% (25/144) [26]	0.318
Thrombocytopenia	3.2% (1/31) [1]	6.9% (4/58) [4]	1.8% (1/55) [1]	4.2% (6/144) [6]	0.365
Cardiac Disorders	**22.6% (7/31) [7]**	**39.7% (23/58) [28]**	**32.7% (18/55) [22]**	**33.3% (48/144) [57]**	**0.557**
Atrial Fibrillation	16.1% (5/31) [5]	19.0% (11/58) [12]	9.1% (5/55) [5]	14.6% (21/144) [22]	0.179
Bradycardia	0.0% (0/31) [0]	1.7% (1/58) [1]	5.5% (3/55) [3]	2.8% (4/144) [4]	0.355
Cardiac Arrest	0.0% (0/31) [0]	0.0% (0/58) [0]	5.5% (3/55) [4]	2.1% (3/144) [4]	0.112
Cardiac Failure Congestive	3.2% (1/31) [1]	5.2% (3/58) [3]	3.6% (2/55) [2]	4.2% (6/144) [6]	1.000
Gastrointestinal Disorders	**16.1% (5/31) [7]**	**20.7% (12/58) [16]**	**21.8% (12/55) [18]**	**20.1% (29/144) [41]**	**1.000**
Dysphagia	0.0% (0/31) [0]	5.2% (3/58) [3]	7.3% (4/55) [4]	4.9% (7/144) [7]	0.712
Gastrointestinal Haemorrhage	9.7% (3/31) [3]	1.7% (1/58) [1]	1.8% (1/55) [2]	3.5% (5/144) [6]	1.000
Nausea	6.5% (2/31) [2]	1.7% (1/58) [1]	10.9% (6/55) [8]	6.3% (9/144) [11]	0.057
General Disorders and Administration Site Conditions	**9.7% (3/31) [3]**	**24.1% (14/58) [15]**	**16.4% (9/55) [10]**	**18.1% (26/144) [28]**	**0.355**
Catheter Site Haematoma	9.7% (3/31) [3]	5.2% (3/58) [3]	1.8% (1/55) [1]	4.9% (7/144) [7]	0.619
Pyrexia	0.0% (0/31) [0]	12.1% (7/58) [7]	10.9% (6/55) [6]	9.0% (13/144) [13]	1.000

Adverse Events occurring at an incidence of 5% or more in any group in the SWIFT Trial					
MedDRA Preferred Term	**Roll-in (all SOLITAIRE™ FR device)**	**Randomized SOLITAIRE™ FR device**	**Randomized Concentric Medical MERCI™ device**	**All Enrolled**	**Rand. p-value**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]	
Infections and Infestations	**41.9% (13/31) [16]**	**43.1% (25/58) [29]**	**34.5% (19/55) [32]**	**39.6% (57/144) [77]**	**0.441**
Pneumonia	9.7% (3/31) [3]	3.4% (2/58) [2]	12.7% (7/55) [7]	8.3% (12/144) [12]	0.089
Sepsis	0.0% (0/31) [0]	5.2% (3/58) [3]	3.6% (2/55) [2]	3.5% (5/144) [5]	1.000
Urinary Tract Infection	32.3% (10/31) [10]	25.9% (15/58) [15]	21.8% (12/55) [13]	25.7% (37/144) [38]	0.664
Metabolism and Nutrition Disorders	**12.9% (4/31) [5]**	**20.7% (12/58) [16]**	**21.8% (12/55) [24]**	**19.4% (28/144) [45]**	**1.000**
Electrolyte Imbalance	0.0% (0/31) [0]	5.2% (3/58) [3]	3.6% (2/55) [2]	3.5% (5/144) [5]	1.000
Hyperglycaemia	6.5% (2/31) [2]	3.4% (2/58) [2]	7.3% (4/55) [5]	5.6% (8/144) [9]	0.430
Hypernatraemia	0.0% (0/31) [0]	3.4% (2/58) [2]	5.5% (3/55) [3]	3.5% (5/144) [5]	0.674
Hypocalcaemia	3.2% (1/31) [1]	3.4% (2/58) [2]	5.5% (3/55) [3]	4.2% (6/144) [6]	0.674
Hypokalaemia	3.2% (1/31) [1]	0.0% (0/58) [0]	7.3% (4/55) [5]	3.5% (5/144) [6]	0.053
Musculoskeletal and Connective Tissue Disorders	**12.9% (4/31) [5]**	**13.8% (8/58) [8]**	**7.3% (4/55) [4]**	**11.1% (16/144) [17]**	**0.363**
Musculoskeletal Pain	6.5% (2/31) [3]	1.7% (1/58) [1]	3.6% (2/55) [2]	3.5% (5/144) [6]	0.612
Nervous System Disorders	**58.1% (18/31) [30]**	**55.2% (32/58) [51]**	**74.5% (41/55) [70]**	**63.2% (91/144) [151]**	**0.048**
Brain Oedema	6.5% (2/31) [2]	5.2% (3/58) [3]	1.8% (1/55) [1]	4.2% (6/144) [6]	0.619
Cerebral Gas Embolism	0.0% (0/31) [0]	1.7% (1/58) [1]	5.5% (3/55) [3]	2.8% (4/144) [4]	0.355
Cerebral Haematoma	12.9% (4/31) [4]	10.3% (6/58) [6]	18.2% (10/55) [10]	13.9% (20/144) [20]	0.286
Cerebrovascular Accident	19.4% (6/31) [6]	12.1% (7/58) [7]	25.5% (14/55) [14]	18.8% (27/144) [27]	0.091
Cerebrovascular Spasm	6.5% (2/31) [2]	5.2% (3/58) [3]	7.3% (4/55) [4]	6.3% (9/144) [9]	0.712
Haemorrhagic Cerebral Infarction	25.8% (8/31) [8]	12.1% (7/58) [7]	9.1% (5/55) [5]	13.9% (20/144) [20]	0.763
Headache	9.7% (3/31) [3]	10.3% (6/58) [6]	3.6% (2/55) [2]	7.6% (11/144) [11]	0.273
Intracranial Pressure Increased	0.0% (0/31) [0]	6.9% (4/58) [4]	5.5% (3/55) [3]	4.9% (7/144) [7]	1.000
Intraventricular Haemorrhage	0.0% (0/31) [0]	3.4% (2/58) [2]	5.5% (3/55) [3]	3.5% (5/144) [5]	0.674
Ischaemic Stroke	6.5% (2/31) [2]	3.4% (2/58) [2]	12.7% (7/55) [7]	7.6% (11/144) [11]	0.089

Adverse Events occurring at an incidence of 5% or more in any group in the SWIFT Trial					
MedDRA Preferred Term	**Roll-in (all SOLITAIRE™ FR device)**	**Randomized SOLITAIRE™ FR device**	**Randomized Concentric Medical MERCI™ device**	**All Enrolled**	**Rand. p-value**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]	
Subarachnoid Haemorrhage	3.2% (1/31) [1]	5.2% (3/58) [3]	14.5% (8/55) [8]	8.3% (12/144) [12]	0.118
Respiratory, Thoracic and Mediastinal Disorders	**25.8% (8/31) [12]**	**37.9% (22/58) [32]**	**41.8% (23/55) [29]**	**36.8% (53/144) [73]**	**0.704**
Atelectasis	0.0% (0/31) [0]	6.9% (4/58) [4]	3.6% (2/55) [2]	4.2% (6/144) [6]	0.680
Hypoxia	0.0% (0/31) [0]	10.3% (6/58) [6]	1.8% (1/55) [1]	4.9% (7/144) [7]	0.114
Pleural Effusion	9.7% (3/31) [3]	0.0% (0/58) [0]	7.3% (4/55) [4]	4.9% (7/144) [7]	0.053
Pneumonia Aspiration	3.2% (1/31) [1]	10.3% (6/58) [6]	5.5% (3/55) [3]	6.9% (10/144) [10]	0.491
Pulmonary Oedema	0.0% (0/31) [0]	5.2% (3/58) [3]	10.9% (6/55) [6]	6.3% (9/144) [9]	0.313
Respiratory Failure	9.7% (3/31) [3]	8.6% (5/58) [5]	14.5% (8/55) [8]	11.1% (16/144) [16]	0.385
Vascular Disorders	**32.3% (10/31) [11]**	**27.6% (16/58) [24]**	**32.7% (18/55) [21]**	**30.6% (44/144) [56]**	**0.682**
Deep Vein Thrombosis	12.9% (4/31) [4]	5.2% (3/58) [3]	9.1% (5/55) [5]	8.3% (12/144) [12]	0.482
Hypertension	0.0% (0/31) [0]	10.3% (6/58) [7]	1.8% (1/55) [1]	4.9% (7/144) [8]	0.114
Hypotension	9.7% (3/31) [3]	10.3% (6/58) [7]	10.9% (6/55) [6]	10.4% (15/144) [16]	1.000
Vasospasm	9.7% (3/31) [3]	5.2% (3/58) [3]	5.5% (3/55) [3]	6.3% (9/144) [9]	1.000

Conclusion:

The data from this study demonstrate that the Solitaire FR device is non-inferior (***p<0.0001***) to the Merci device in achieving arterial recanalization of the occluded target vessel without any presence of symptomatic intracranial hemorrhage. At 30 and 90 days, Solitaire FR had higher rates of GNO compared to Merci. Further, mortality rates and rate of intracranial hemorrhage within the Solitaire FR treated group were lower than those seen in the Merci treated group. The overall safety profile of the two devices, as measured by the rate of device-related and procedure-related SAEs, was similar between the two groups. Data from this study demonstrate that the Solitaire FR device is safe, effective, and non-inferior to Merci for arterial recanalization of occluded target vessels after acute ischemic stroke in subjects who are ineligible for or have failed IV t-PA therapy.

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Irvine, CA 92618

MAR - 2 2012

Re: K113455
Trade/Device Name: Solitaire™ FR Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NRY
Dated: January 27, 2012
Received: January 30, 2012

Dear Ms. Heaton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113455

Device Name: Solitaire™ FR Revascularization Device

Indications for Use: The Solitaire™ FR Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey Toy

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113455